COMMUNITY ACCESS NATIONAL NETWORK

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November 11, 2025

Colorado Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: UPL Next Steps

Dear Honorable Members of the Colorado Prescription Drug Affordability Board,

Today, we write with concerns regarding ongoing rulemaking and UPL development.

The **Community Access National Network (CANN**) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

Responsibility for Unintended Consequences is Questionable

The Board acknowledges that non-medical switching, adverse tier adjustments, and formulary exclusions are potential outcomes of unfavorable UPL selection. However, the Board's sentiment is to urge stakeholders to reach out to legislators, since actions such as ensuring drugs assigned a UPL are not removed from formularies by plans require legislative protection. This presents as an abdication of responsibility for potentially adverse outcomes. These issues have been raised several times in the past, giving the Board ample time to inform the legislature of them. In addition to the responsibility of exploring non-UPL solutions, raising awareness of the absence of safeguards to protect stakeholders is also a responsibility of the Board's General Assembly reporting.

Extension of Time to Implementation is a Good Decision

The adopted rule states that the UPL will not take effect until January 2027. We support this, especially since, as of the last meeting, staff at this stage are trying to figure out the monitoring and implementation details. It is encouraging that energy is now being dedicated to determining which data and metrics should be measured for monitoring and implementation. However, as mentioned multiple times in the past, data points such as monitoring metrics should have been established much earlier in Board processes. Indeed, monitoring metrics would have emerged from a proper cost-benefit analysis.

Methodology Remains Unclear

A methodology is a planned and structured procedure for solving a problem or achieving a predefined goal. A practical methodology is one described in a way that allows peers and others to repeat the process to achieve the same outcome. The Board has expressed that it is not possible to set forth a concrete methodology because all drugs are different. However, regardless of the drug in question, any methodology requires defining the problem, explaining the drivers causing the problem, defining the desired outcome, and explaining how the stated solution specifically addresses that definition.

There does not appear to be a fleshed-out methodology for the Enbrel UPL that is repeatable and explainable. Relying on the CMS MFP for Enbrel as a convenient number is not a methodology.

A benchmark is a standard or a point of reference against which things may be compared or assessed. There is no evidence of analysis or research into multifactorial baseline data across multiple affordability aspects, where the outcomes of other potential UPLs were compared with the MFP. Additionally, rounding up the UPL to $600.00, which is just a few dollars above the actual MFP for no other reason than to ensure it is not colored as being directly linked to the MFP or to allow a margin of adjustment as MFP changes, is not an evidence-based methodology.

Presenting plan-payer APC data amounts and then stating that using the MFP would result in lower costs is not an evidence-based methodology. ***It is simply stating two different numbers where one is lower than the other***.

We also wish to reiterate our previously voiced concern about the overreliance on APC data, which is essentially flawed, not reflecting patient experience, which directly impacts patient affordability and access via benefit design. Similarly, APC data does not reflect profit-driven PBM motives in the tier structures that define patient cost-sharing amounts. Simply put, APC data is not a sufficient basis upon which to rely to define "affordability". Regardless of the PDAB's repeated use of this metric, APC remains a poor substitute for actual data gathering, accessibility metric monitoring, and policy-making.

There has been a repeated Board sentiment that manufacturers would not have agreed to MFP if it were financially harmful for them. Several stakeholders have pointed out that the MFP mechanisms were not a mutual negotiation process in which two parties of equal footing sat down at the negotiating table. CMS required manufacturers to agree to the terms before knowing them, with penalties of being locked out of the Medicare system if they did not agree. Most importantly, there is little explanation of how CMS arrived at the MFP number it settled on. With no framework for understanding how CMS arrived at Enbrel's MFP, and without proper analysis of Colorado's status quo, what methodology leads to the belief that the CMS MFP is what Colorado needs?

It is worth noting that medications selected for price caps by CMS are in their first stages of plan design changes, which this Board has not had the chance to review. Upon information and belief, CANN expects patients to be adversely affected by adverse tier changes, increasing patient costs.

Adopting the MFP as the basis for the UPL, without analyzing or modeling actual system and stakeholder needs, is not an evidence-based methodology. It is latching onto a convenient number and hoping for the best.

A UPL Does Not Operate in the Same Manner as an MFP

The CMS MFP program operates in a manner that attempts to make providers and pharmacies whole. Pharmacies and providers are required to pay manufacturers' acquisition costs while only being reimbursed at the MFP rate. Subsequently, claims are filed, and manufacturers pay pharmacies and providers the difference. A state UPL does not provide that attempt at financial saliency. A UPL set below the acquisition cost leaves purchasers at a loss. Currently, there has been no mention of suggesting additional appropriations to make up for that loss. A UPL is not a negotiated contract of acquisition prices. This is especially true for out-of-state wholesalers from where many pharmacies source medications.

The last meeting indicated that, now that a UPL has been set, staff is drafting letters as part of the manufacturer inquiry process to give manufacturers, such as Amgen, the opportunity to indicate whether they will make Enbrel available in Colorado at the UPL price. However, that description of inquiry is overly simplistic. Clarity on the inquiry letter details is needed, especially if the answer to the inquiry is 'no'. Because there is no evidence-based methodology for the current UPL's selection, what will the Board use as a foundation for offering another number?

As a non-patient issue, it is simply bad business to seek manufacturer agreement *after* issuing a mandate and during active litigation. It is neither reasonable nor rational to seek manufacturer agreement for a UPL at this late stage. It does, however, prove a tacit admission on the Board's part that a UPL is explicitly designed to pick winners and losers, or to otherwise coerce a private entity with complete humanitarian disregard for patients who might otherwise be negatively affected by losing access. From the patient perspective in observing this potential approach, the Board appears to be leveraging patient access (otherwise considered a potential consumer pool) as hostages in a business negotiation.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

We appreciate the time and effort the Board has put into this endeavor. Unfortunately, we are concerned that this UPL and the process leading up to it are irresponsible ways to simply put something in motion and hope for the best.

Respectfully submitted,

Ranier Simons
Director of State Policy, PDABs
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

EACH PIC COALITION

January 7, 2025

Colorado Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: Public Comments on the Stakeholder Workgroup Recommendations

Dear Members and Staff of the Colorado Prescription Drug Affordability Board:

On behalf of the Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC), we are pleased to submit information to the board on the recommendations set forth by the PDAAC Stakeholder Workgroup on patient engagement. We have provided our comment letter that was submitted to the PDAAC below, prior to the final workshop, so that the board can review and consider our feedback in whole.

In addition to the feedback below, we would also like to emphasize and support the recommendation made by the Color of Gastrointestinal Illnesses in their comment letter submitted in conjunction with the last workshop. We also urge the board that if, “data indicates that an Upper Payment Limit will not resolve the affordability challenges facing patients, the PDAB must be open to considering whether an affordability review is a constructive use of its resources.”

We appreciated the opportunity to participate in the workgroup sessions and shape recommendations intended to strengthen patient engagement and transparency. Ultimately, however, the success of any policy changes will depend on how they are implemented and modeled by the board itself. The board sets the tone for how patient organizations and patients are viewed, engaged, and treated throughout the PDAB process.

We urge the board to foster a culture of trust, respect, and consistency. Any policies related to transparency or conflicts of interest must be applied equally and universally. Patient organizations play a critical role in elevating lived experience, and effective engagement depends on the board demonstrating that those perspectives are valued and welcomed.

At every stage, including identifying solutions, affordability should remain centered on patients and the realities they face in accessing and affording their medications. We offer these comments based on both our workgroup participation and our broader experience engaging with PDABs nationwide, in the spirit of supporting a credible, inclusive, and patient-focused process.

Thank you for your consideration. We remain available as a resource as the board continues its work and look forward to seeing the updated draft.

Sincerely,

Tiffany Westrick-Robertson

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

PATIENT INCLUSION COUNCIL

Tiffany Westrich-Robertson
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Patient Inclusion Council (PIC) Coalition Lead

December 9, 2025

Colorado Prescription Drug Affordability Advisory Council
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: Public Comments on the PDAAC Report Best Practices for Patient Engagement

Dear Members of the Colorado Prescription Drug Affordability Advisory Council (PDAAC):

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

Successful Reforms Center Patient Experiences

Our goal is to ensure that policy interventions, particularly those developed by Prescription Drug Affordability Boards (PDABs), are informed by the realities patients face in affording and accessing their medications.

Patients across the country have reported that the way affordability is currently assessed often does not reflect their lived experience. Common tools tend to ask yes/no questions about whether a single drug is “affordable,” without asking why a patient perceives it that way. This lack of qualitative insight can lead to affordability determinations and policy responses that do not address the underlying drivers of hardship.

We share the council’s commitment to lowering prescription drug costs for Coloradans. Achieving that goal requires a process that starts with and ends with patients. The advisory council and board must focus on patients’ lived experience, their real barriers, and addressing the challenges they report are the cause of affordability issues. We welcome the opportunity to collaborate on designing improved patient engagement processes for future reviews.

EACHPIC COALITION

Item 1. Enhance the PDAAC's Scope

While we applaud the council for recognizing that patients must be included in the metrics that the board should consider when selecting drugs for affordability review, we caution that providing a summary of patient feedback is not enough. Specifically, the same rigor applied to data collection during drug reviews should also apply at this stage, including clear metrics for evaluating patient responses. Accordingly, the recommendation to "conduct a trend analysis to identify drugs patients recommend for review" should be revised to better determine not only if affordability challenges exist, but what is driving those challenges so that appropriate policy remedies can be sought.

Our Patient Experience Survey demonstrates why rigor in data collection is essential at this early stage:

- Affordability is often disconnected from drug cost. Patients across all cost ranges—including those paying $0–$10—reported unaffordability driven by insurance changes, denials, and broader medical expenses.
- Affordability and access are intertwined. Among patients who said they stopped taking a drug for affordability reasons, 100% cited insurance-related barriers, not price itself.
- Insurance design and financial assistance—not drug type or price—are the strongest predictors of affordability. Seventy-one percent of patients using specialty drugs with financial assistance reported affordability, compared to only 38% without assistance.
- Several respondents cited unaffordability based on opinions about the retail cost of drugs, not their actual out of pocket costs.

These findings illustrate that focusing narrowly on the price of an individual drug will not address the core issues patients face. Expanded engagement early in the process can also help identify correctable barriers, such as utilization management practices, accumulator policies, or lack of access to assistance programs, long before policy decisions are made.

Additionally, we recommend that all raw patient input collected by the council or board be made public in its full, unedited form (with appropriate privacy protections). As we have observed in other states, summarized or filtered data often lacks the nuance needed to understand patient experiences and can unintentionally distort the meaning of patient testimony.

Item 2. Establish a PDAB Patient Engagement Toolkit

We appreciate that several of the recommendations outlined in this section reflect the same best practices we have consistently advanced nationwide. We stand ready to collaborate with the council and the board to help shape patient-facing resources and ensure they are accessible, accurate, and aligned with how patients communicate and share their experiences.

However, for this collaboration to be effective, it must be accompanied by a good-faith commitment from board members to respect the contributions of patient organizations. In past Colorado PDAB processes, some patient organizations have experienced skepticism or dismissal of their perspectives. A successful engagement toolkit requires not only strong materials, but also a culture that values and trusts patient-centered expertise.

Furthermore, even the strongest toolkit will fall short without a practical, well-funded outreach strategy. Without dedicated resources for public education, advertising, and community outreach, patient engagement efforts will not break through the crowded landscape of information competing for public attention. Meaningful engagement requires proactive and adequately resourced communication.

Regarding patient-facing surveys and focus groups, we appreciate the council's willingness to collaborate with patient research partners (PRPs) on data collection efforts. As a reminder, a PRP is a patient who has experience working with research teams and whose expertise should be considered equal to other professionals; they are not advisors. The Patient Inclusion Council (PIC) is positioned to help the council identify individuals with this level of experience.

Item 3. Create a Communication Network

Expanding engagement channels is an important goal, but the process for selecting outreach partners must be broad, transparent, and inclusive. Ensuring that no group is marginalized, particularly groups raising concerns about current PDAB processes, is essential for a credible and inclusive engagement network.

Item 4. Provide Additional Assessment Information

We again urge the council to move beyond summaries and instead provide full transparency by publishing all survey responses and input materials, with appropriate redactions for privacy. As our Patient Experience Survey illustrates, open-ended narratives are often where the real insight resides.

Summaries that lack context behind affordability challenges or identify underlying access barriers tend to flatten nuance, making it difficult to understand the real drivers. Transparency is a foundational requirement for trust, both among patient communities and within the broader stakeholder ecosystem.

Item 5. Promote a Process for Voluntary Disclosure of Conflicts of Interest (COI)

We appreciate the council's acknowledgment that the board has on more than one occasion demonstrated an attitude of dismissal and distrust towards patient organizations. We broadly agree with the underlying belief of the duality of interest approach - that all stakeholders have merit and deserve to share their views.

However, we strongly caution that implementing new disclosure requirements will only be effective if the board first demonstrates a commitment to treating all organizations, even those with "dual interests", with respect and without presumption of bias.

A voluntary disclosure framework can help build trust, but only if it is applied universally and is paired with meaningful cultural change within the board. Further, we urge that all COI statements should be open ended to allow submitters to provide context regarding the acceptance and use of any and all donor funding.

Without such change, additional disclosures risk being misused to marginalize stakeholder voices rather than enhance transparency. We urge the council to recognize that creating a culture of trust is not the responsibility of stakeholders alone, the board must lead by example.

Conclusion

Thank you for your ongoing work to improve drug affordability. We look forward to the opportunity to work alongside you to ensure that affordability reviews translate into meaningful improvements in patient access, equity, and health outcomes.

Sincerely,

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Ensuring Access through Collaborative Health (EACH) Coalition Lead

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Via Electronic Submission

November 10, 2025

Gail Mizner, MD
Colorado Prescription Drug Affordability Board Chair
Colorado Division of Insurance
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Denver, CO 80202
dora_ins_pdab@state.co.us

Dear Dr. Mizner:

Johnson & Johnson Innovative Medicine ("J&J") resubmits the following comments, initially transmitted to the Colorado Prescription Drug Affordability Board ("PDAB" or "Board") on September 29, 2025. These comments pertain to the PORTAL "Presentation on STELARA Biosimilars," ("PORTAL Presentation"), which was placed on the July 11, 2025 and August 22, 2025 Board meeting agendas. Given that the PORTAL Presentation was missing from the October 3, 2025 meeting agenda, J&J respectfully reiterates our request that the Board cancel plans to move forward with an upper payment limit ("UPL") rulemaking for STELARA® (ustekinumab).

A. STELARA's UPL rulemaking should be cancelled because biosimilars are available.

As previously noted, when selecting drugs for affordability review, the Board initially ranked HUMIRA® first on its list of eligible drugs but ultimately excluded HUMIRA due to the availability of biosimilars.[1] Similarly, as communicated in our July 9, 2025 letter, the FDA has approved at least seven ustekinumab biosimilars and an unbranded ustekinumab biologic since the PDAB's affordability reviews began.[2] In response to our request for consistent treatment of STELARA and HUMIRA, the PDAB added the PORTAL Presentation to the July 11, 2025 and August 22, 2025 Board meeting agendas, although time constraints prevented its discussion.[3] We respectfully emphasize that the existence of FDA-approved ustekinumab biosimilars should be sufficient to cancel STELARA's UPL rulemakings based on the PDAB's previous actions with HUMIRA. Continuing with STELARA rulemaking when the Board did not do so for similarly-situated Humira would constitute inconsistent treatment and an arbitrary and capricious

[1] CO PDAB 2023 Eligible Drug Dashboard, Tableau, https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/2_PrioritzedSummaryList (last visited June 20, 2025).

[2] FDA, *Purple Book: Database of Licensed Biological Products, Keyword "Ustekinumab,"* https://purplebooksearch.fda.gov/ (last visited June 20, 2025).

[3] CO PDAB, Prescription Drug Affordability Board Meeting Agenda, Friday, July 11, 2025 from 10:00 am – 1:00 pm, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://doi.colorado.gov/sites/doi/files/documents/July%2011%20Draft%20Agenda.pdf (last visited July 8, 2025).

determination.

If the Board does review the PORTAL Presentation at an upcoming meeting, it is important to note that the Presentation arbitrarily distinguishes between STELARA and HUMIRA. The PORTAL Presentation does not contain any data or analysis of HUMIRA to justify why the two drugs would be treated differently by the PDAB in assessing which drugs to select for affordability review. Additionally, the Presentation contains inaccurate generalizations, such as claiming that ustekinumab biosimilar coverage is currently limited. Yet, the "Formulary Coverage" chart contained within the Presentation shows up to 83% of commercial and exchange plans and up to 69% of Managed Medicaid plans cover at least one, if not multiple, ustekinumab biosimilars as of July 1, 2025.

As of October 1, 2025, Health First Colorado's Preferred Drug List shows that all seven ustekinumab biosimilars, unbranded Ustekinumab, and STELARA are covered for psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis; however, all nine products, including STELARA, are non-preferred.[4] The prior authorization requirements to access STELARA are the most stringent.[5] This trend to restrict STELARA access is consistent with recent analysis of 2026 formularies, which shows that PBMs are beginning to place STELARA on exclusion lists and cover multiple biosimilars instead.[6]

B. STELARA'S UPL hearings should be cancelled because the "verified" data shows significant decreases in spending over time.

We reiterate that the "Addendum to the 2023 Affordability Review Summary Report: STELARA" supports cancelling any planned UPL rulemakings. These "verified" numbers show significant reductions in spending across all categories (total paid, average paid per person, total patient paid, average out of pocket) (see image below).

Moreover, as this data is outdated, it does not reflect the current market. Across our portfolio, J&J's net prices have declined by a compounded 18.2% since 2016, and our rebates, discounts, and fees to middlemen, private insurers, and other entities continued to grow, reaching $47.8 billion in 2024.[7] These discounts, rebates, and fees accounted for 58% of every dollar in J&J's

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[4] *Colorado Department of Health Care Policy and Financing Preferred Drug List (PDL) Effective October 1, 2025*, Health First Colorado, https://hcpf.colorado.gov/sites/hcpf/files/10-01-25%20PDL%20V2.pdf (Sept. 30, 2025).
[5] *Id.*
[6] *The Stelara Biosimilar Price War: How PBM-Affiliated Private Labels Are Reshaping the Market*, Drug Channels (July 8, 2025), https://www.drugchannels.net/2025/07/the-stelara-biosimilar-price-war-how.html (last visited Sept. 29, 2025); Adam Fein, *Buh Bye Stelara! Hello, ESI's Private Label Play*, LinkedIn, https://www.linkedin.com/posts/adamjfein_pbm-activity-7373470406009167872-yE75/?utm_source=costcurve.beehiiv.com&utm_medium=newsletter&utm_campaign=it-s-formulary-season-and-early-analyses-suggest-big-changes-in-how-pbms-approach-biosims&_bhlid=1c2f29618da22fa2c2f981580fad0fb7bcf4aa9f (last visited Sept. 29, 2025).
[7] *Patient Access and Affordability: 2024 Johnson & Johnson Innovative Medicine U.S. Pricing Transparency Data*, (2025), https://policyresearch.jnj.com/2024transparencyreport (last visited Sept. 29, 2025).

gross sales.[8] STELARA is no exception, and we would expect to see spending continue to decrease given robust biosimilar competition. Therefore, J&J respectfully urges the Board to cancel any future UPL rulemaking for STELARA.

Annual Utilization and Expenditures (All Lines of Business/Pharmacy Claims)

Table 10 shows the percent change in the Annual Utilization and Expenditures for Stelara in 2019-2022.

	Percent Change			
	2019	2020	2021	2022
Patient Count	-2%	-3%	-5%	-5%
Total Paid	-1%	-12%	-30%	-28%
Average Paid Per Person	3%	-13%	-28%	-33%
Total Patient Paid	0.1%	0.1%	-2%	-15%
Average Out-of-Pocket (OOP)	-28%	-33%	-30%	-32%

Finally, we share the concerns raised in Amgen's lawsuit about the validity of the Board's rulemaking process and the conflict with federal patent law.

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address gaps in affordability and access as well as protect our nation's leading role in the global biopharmaceutical innovation ecosystem. We know that patients are counting on us to develop, bring to market, and support access to our medicines. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives. We thank you in advance for taking our recommendations into account.

Sincerely,

Michael J. Valenta

Michael Valenta
Vice President, Value, Access & Pricing, Strategic Customer Group
Johnson & Johnson Healthcare Systems, Inc.

[8] *Id.*

November 12, 2025

Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway
Denver, CO 80202

TO: Members of the Colorado Prescription Drug Affordability Board

As a physician with decades of experience caring for patients whose families often struggle to access and afford necessary medications, I continue to find the concept of Upper Payment Limits (UPLs) deeply troubling. Implementing a list price cap on Enbrel and future medications will predictably restrict access to essential treatments and deserves more input from the patients who would be most adversely affected and the clinicians who care for them.

Since the Board has moved forward with establishing the UPL, it is now critical that you implement robust accountability measures to ensure this untested theory achieves its intended outcomes. The fundamental question facing the Board is: How will you prove that your approach works? What specific metrics will demonstrate that the UPL saves money for the people you claim it will benefit? If the purpose of the UPL is to reduce what Coloradans pay for their medications, the Board must establish clear metrics showing that patients, not just state purchasers or insurers benefit. Simply imposing a payment cap does not automatically translate to lower patient costs if pharmacy benefit managers, insurers, and other intermediaries do not pass the required lower prices and implied savings through to beneficiaries. Further, will the Board measure whether patients actually experience reduced out-of-pocket health care (not just drug) costs, maintain access to necessary medications, or avoid harmful health outcomes due to treatment disruptions?

With the UPL now established, what accountability mechanisms will track its effectiveness? Focusing solely on the list price as a mechanism to improve patient treatment costs ignores the reality that Colorado's multi-faceted drug pricing ecosystem involves insurers, pharmacy benefit managers, wholesalers, and manufacturers, all of whom influence what patients ultimately pay.

Coloradans and their elected representatives deserve recommendations grounded in thorough, inclusive stakeholder engagement. Clinicians and patients alike worry that the Board's current deliberations still lack the full benefits of this real-world input. Many Coloradans depend on

specialized, innovative, and unfortunately expensive therapies. Enacting a UPL is only the first step. Proving it works requires rigorous, ongoing measurements and transparency that the Board has not yet demonstrated. Without clear evidence that the UPL delivers meaningful savings to patients while maintaining access to necessary medications, this policy risks becoming an exercise in cost-shifting rather than genuine affordability reform.

I implore the Board to pause and reconsider the UPL approach before implementing this policy that restricts access rather than improves affordability. State and national clinicians and patients are committed to working with you to ensure affordable medications for all Coloradoans, through a more thorough, comprehensive, extensive and patient-focused consideration process. No policy is preferable to bad policy, and if a problem is predictable, it is potentially preventable.

Thank you for your attention to this critical issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, MACR

Board Member, Let My Doctors Decide Action Network